

**REMARKS**

The Amendment, filed in response to the Office Action mailed July 9, 2008, is believed to be fully responsive to all issues raised in the Action. A favorable reconsideration on the merits is respectfully requested.

Upon entry of the amendment, which is respectfully requested, claims 11 and 20-36 are all the claims pending in the application. Claims 29-34 are withdrawn from consideration as being directed to non-elected invention. Claims 11, 21-23, 26, and 27 are currently amended to more clearly set forth the claimed subject matter. Claims 35-36 are newly added. Support for new claims 35 and 36 may be found by the disclosure of the original specification and original claims 27 and 28, respectively. No new matter is introduced.

***Restriction and Election of Species Requirements***

Claims 11 and 20-34 are pending in the application and claims 11 and 20-34 are considered. Claims 29-34 are withdrawn from consideration as being directed to non-elected invention.

The Examiner has acknowledged Applicant's election without traverse of Group I, encompassing claims 11 and 20-31 and the species (5Z, 9 $\beta$ , 11 $\alpha$ , 13E)-17,17-propano-11,16-dihydroxy-9-chloroprostano-5,13,19-trienoic acid.

In response to the Applicant's statement that the submission of sworn English translation of foreign priority document perfects the claim priority date to July 25, 2003, and thus obviating the Examiner's grounds of the Lack of Unity, the Office asserts that Paralkar (European Patent Application EP 1 205 189) teaches a method of promoting bone growth comprising a prostaglandin agonist. In this regards, Applicants note that the Restriction is not made final.

Claim 11 is amended to limit its active ingredient to EP<sub>2</sub> agonist, which was elected in response to the Restriction and Election Species Requirement.

***Information Disclosure Statement***

In the Office Action, the Office states that the Information Disclosure Statements filed on January 25, 2006 fails to comply as legible copies of the foreign references have not been provided.<sup>2</sup> The Examiner admits that the references are listed in International Search Report (ISR), but asserts that merely listing the documents cited in the ISR is not considered to be a proper citation complying with 37 C.F.R. § 1.98(a)(2).

Applicants respectfully submit that, as a result of an agreement among the European Patent Office (EPO), Japan Patent Office (JPO), and the United States Patent and Trademark Office (USPTO), copies of documents cited in the ISR issued by any one of these International Searching Authority Offices generally are being sent to the other Offices when designated in the international application, and Applicants are not required to submit copies of the documents cited in the ISR. MPEP 1893.03(g). In the instant application, as the ISR was prepared by JPO and Applicants believe that a submission of copies of the references cited in the ISR is not required. Furthermore, as the Office correctly indicates, Applicants note that the references cited in the ISR have been disclosed to the Office by submitting copies of corresponding or equivalent references as IDS. Applicants provide the following Table showing the list of references cited in ISR and corresponding references submitted in the IDS.

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<sup>2</sup> Specifically, of JP 2001-220357, JP 2000-507961, JP 11-193268, JP 2001-527063, JP 2000-95755, JP 2000-128858, WO 98/34916, JP 2002-179595, JP 6-227985, WO 02/16311, WO 02/20462 and WO 03/16254

References cited in the ISR	Corresponding Document written in English (already submitted as IDS)
JP 2001-220357	EP 1121939
JP 2000-507961	WO 98/27976
JP 11-193268	EP 860430
JP 2001-527063	US 6262293
JP 2000-95755	US 6235780
JP 2000-128858	EP 860430
WO 98/34916	US 6288119
JP 2002-179595	EP 1205189
JP 6-227985	EP 445948
WO 02116311	EP 1312601
WO 02/20462	EP 1314719
WO 03/16254	EP 1431267

### ***Specification***

The Office has indicated that the attempted incorporation of subject matter into this application by reference to WO 98134916, JP-A-61-249951, JP-A-8-239356, US 4,692,464 and US 4,863,961 is ineffective because the root words "incorporate" and/or "reference" have been omitted.

In response, Applicants incorporate the disclosures of the mentioned patents by reference by amending the specification.

Therefore, withdrawal of the objection is respectfully requested.

### **Responses to Claim Rejections Under 35 U.S.C. § 112**

#### **1. "And/or"**

In the Office Action, claims 11, 21, 22, and 26 stand rejected on the grounds that the recitation "and/or" in the claims is confusing as to what method is being claimed.

In the currently amended claims, the term "and/or" is deleted from claims 11, 21, 22, and 26, rendering the rejection moot.

#### **2. Rejection under 35 U.S.C. § 112, first paragraph**

In the Office Action, claims 27 and 28 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as well as enabling disclosure requirement. Regarding the written description requirement rejection, the Office Action, page 7 states “Specifically, instant claim 27 discloses ‘substances having ... a compound described in WO 98/34916,... US 4,863,961,’” which appears to be incorrect recitation, as original claim 27 does not refer to the any of the above references.

Applicants amend claim 27 to delete the recitation of patent reference numbers and, instead, refer to specific chemical formula, rendering the rejection moot. The compounds defined in the amended claim 27 are described in the references recited in original claim 27, and thus amended claim 27 is supported by the disclosure of the specification, which makes reference to the patent publications recited in original claim 27.

Regarding the enablement rejection, Applicants respectfully disagree with the Office. Claim 28 recites specific compounds. These compounds are described by their chemical name (i.e., structure) and the specification describes how to make and use the recited compounds.

Accordingly, it is believed that the rejection is not sustainable and its withdrawal is respectfully requested.

### **3. Rejection under 35 U.S.C. § 112, second paragraph**

In the Office Action, claims 11 and 21-28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office points out that the indication of the group or subject to be treated and the indication for which treatment is given is critical or essential to the practice of the invention, but not included in the claim(s).

It appears to Applicants that claim 20 is inadvertently missing in this section 112, second paragraph, and Applicants argument applies to claim 20.

In response to the rejection, claim 11 is amended to recite “to a subject in need of stimulating chondrocyte growth,” rendering the rejection of claim 11 and its dependent claims moot. Therefore, withdrawal of the rejection is respectfully requested.

### **Response to Claim Rejections Under 35 U.S.C. § 103**

In the Action, claims 11 and 21-28<sup>3</sup> stand rejected under 35 U.S.C. 103(a) as being unpatentable over Paralkar (European Patent Application EP 1 205 189) (“Paralkar”), in view of Tani *et al.* (“Development of a Highly Selective EP2-receptor Agonist. Part 2: Identification of 16-Hydroxy-17, 17-trimethylene 9beta-chloro PGF Derivatives,” 2002, Bioorganic and Medicinal Chemistry, Volume 10, Pages 1107-1114) (“Tani”) and Fortier *et al.*, (Insulin-like growth factor-I enhances cell-based repair of articular cartilage,” 2002, J Bone Joint Surg, Volume 84-B, Pages 276-288) (“Fortier”).

Applicants respectfully traverse.

Paralkar is directed to a *combination of* a prostaglandin agonist (including selective EP2 or EP2 agonists) and a HMG-CoA reductase inhibitor, the combination being used to stimulate bone growth. Paralkar also teaches that the combination therapies can be used for limiting or treating cartilage defects or disorders. Paragraph [0038]. Thus, in Paralkar, the prostaglandin agonist (including selective EP2 or EP2 agonists) and a HMG-CoA reductase inhibitor *both are essential active ingredients*.

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<sup>3</sup> It appears that the rejection under 35 U.S.C. § 103(a) inadvertently misses claim 20. Applicants argument on the section 103(a) rejection applies to claim 20.

To the contrary, the currently presented claim 1 and its dependent claims clearly set forth the subject as consisting essentially of a substance having an EP2 agonist activity. *See also*, page 4, lines 2-3 of the specification.

Applicants further submit that the Office's statement "EP 1205189 describes that 'representative uses of the therapy comprising an EP2 selective agonist is to limit or treat cartilage defects or disorders,' mischaracterizes the teaching of EP 1205189. In paragraph 38 of EP 1205189, there is a description that "*the combination therapies* of the present invention (the combination of a prostaglandin agonist and a HMG-CoA reductase inhibitor) can be used for limiting or treating cartilage defects or disorders, and may be useful in wound healing." This description relates to "*the combination therapy* of the prostaglandin agonist and the HMG-CoA reductase inhibitor", and *it does not teach that prostaglandin by itself is effective for treating cartilage-related disease*. Moreover, it does not teach that EP2 agonist which is particularly selective among prostaglandin promotes the formation of cartilage by itself.

Therefore, it is believed that the rejection is not sustainable and its withdrawal is respectfully requested.

#### **New Claims 35-36**

Newly added independent claim 35 and dependent claim 36 are patentable over the references cited. Claim 35 and 36 each recite a certain aspect of subject matter defined in claims 27 and 28, respectively. None of the references discussed above teaches or renders claims 35 or 36 obvious, at least for the same reasons discussed above with respect to claim 27.

### CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588**.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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